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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,053	06/24/2003	Dean R. Thompson	10021004	1897

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AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,053

Applicant(s)

THOMPSON ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 5,12,25 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-11,13-24,26-30 and 32-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/24/03;2/22/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's election without traverse of claims 4, 10, and 32 of Species A and claims 12 and 32 of Species B in the reply filed on 8 September 2006 is acknowledged. Claims 5, 12, 25, and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8 September 2006.

Priority

Priority to US application 10/388,088, filed 13 March 2003 is hereby denied. The application to which Applicant claims priority does not disclose the limitations of the instant invention. The application fails to disclose the correlation matrix and the clustering of the correlation matrix, as is instantly claimed, therefore, priority to this application is denied.

Information Disclosure Statement

The Information Disclosure Statement filed 24 June 2003 has been partially considered. Several references have been lined through, as they do not contain a publication date. The Information Disclosure Statement filed 22 February 2005 has been fully considered. Signed copies of PTO forms 1449 are included with this Office Action.

Drawings

The drawings filed 24 June 2003 are accepted.

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Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 6-11, 13-24, 26-30, and 32-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to a method and computer program product for identifying related ions in an input data set. The methods of correlating, clustering, selecting, and producing a spectrum do not equate to physical method steps and therefore, no physical transformation of matter is associated with such steps, as required under 35 USC 101 for statutory subject matter. Absent a physical transformation of matter a claim may be statutory if it provides a concrete, tangible and useful result. However, no **specific** outcome is set forth in the claims such that the steps of the method produce a result that is immediately concrete, tangible, and useful. The output is not clearly defined, as being a tangible output, for instance, to a user and therefore, the claim is non-statutory. The claims must, **as a whole**, satisfy section 101 and must be for practical application, which can be defined as:

1. The claimed invention “transforms” an article or physical object to a different state or thing.
[*The claimed invention in the instant case does not transform any physical object or article.*]
2. The claimed invention otherwise produces a useful, concrete, and tangible result, based upon various factors (see below) [*The claimed invention in the instant application does not produce a concrete, tangible, and useful result. There is not output to a user, for example, that results in a tangible result*].

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In addition, the program product has machine executable code, however it is not embodied on a physical medium. Further, the program product of the instant claims does not provide that the execution of the code accomplishes a practical application (i.e. results in a *physical* transformation or produces a concrete, tangible, and useful *result*) and is therefore, non-statutory. There are no further means that provide for the practical application of results in a concrete, tangible, and useful form, as in a means for output to a user, for example, and therefore, the claims are non-statutory.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 6-11, 13-24, 26-30, and 32-40 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility.

The instant claims are directed to a method of identifying related ions and a computer program product for doing the same. The specification teaches that mass spectroscopy is useful for elucidating the structural and chemical properties of molecules (page 1). Further, the specification states that the instant invention is related to mass spectral analysis and processing mass spectra. However, the claimed method, while reciting "a method for identifying related ions in an input data set", does not include steps such that one of skill in the art would know the use for identifying related "ions" by correlating data, clustering a matrix and producing a spectrum that is undefined. The specification does not teach any specific, substantial, or well-

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established utility for a method that simply inputs random data, outputs random data, and establishes no relationship between a resultant spectrum and a time period. Utilities that require further research to identify or reasonably confirm a real-world context of use are not substantial utilities (See MPEP 2107.01). Therefore the claimed method does not have utility.

Further, merely computerizing a method that otherwise does not meet the utility requirements of 35 USC 101 does not render that method “useful” (e.g. merely drawing a picture does not have utility, nor does the method render utility to the scene to be drawn nor the finished picture. Having the computer “render” the same drawing does not render the drawing or the method of creating it “useful.” The method steps are merely those of inputting and outputting data, similar to rendering a drawing (input data = the scene; output = the drawing), and thus do not have a substantial nor a specific utility. The input and output data are not limited to be anything in particular, such that the data (or result) itself imparts utility to the method, therefore neither the method steps nor the result of the method imparts utility.

Claims 1-4, 6-11, 13-24, 26-30, and 32-40 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-4, 6-11, 13-24, 26-30, and 32-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 20, and 21 recite, “a method (or program product) for identifying (or quantifying) related ions in an input data set comprising correlating each row of data in an input data set”. It is unclear what data is being input in each row. Is it the ions that are represented in each row? The claim further states that “each row representing intensities over time”. Is that the intended “input” for the row? Clarification is requested.

Claims 1, 20, and 21 recite, “each element of said correlation matrix”. There is insufficient antecedent basis for “each element” in the claim. Clarification is requested.

Claims 1, 20, and 21 recite, “said correlation matrix including a correlation value”. It is unclear what the correlation value represents. What is it a correlation of? Clarification is requested.

Claims 1, 20, and 21 recite, “clustering said correlation matrix identifying at least one group and at least one row”. It is unclear if it is the matrix that is identifying the at least one group or if it is the clustering of the matrix that identifies one group. Clarification is requested.

Claims 1, 20, and 21 recite, “selecting at least one time period”. It is unclear from what the time period is being selected. Is it the time period representing a particular intensity or some other time period? Clarification is requested.

Claims 1, 20, and 21 recite, “producing a resultant spectrum”. This is unclear, as no spectra were input such that a spectrum would be output. Clarification is requested.

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Claims 1, 20, and 21 recite, “a method for identifying (quantifying) related ions”.

However, there is no step of identifying or quantifying related ions in the claims. Does a resultant spectrum equate to identification or quantification of related ions? Clarification is requested.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 20, 21, and 40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28 and 30 of copending Application No. US 11/145,459, filed 2 June 2005 in view of US 2004/0096982 (filed 19 November 2002; PTO form 1449).

Claims 1, 20, 21, and 40 of the instant application are drawn to a method and computer program product for identifying or quantifying related ions in an input data set comprising correlating data to produce a correlation matrix, clustering the matrix, selecting a time period, and producing a resultant spectrum.

Claims 28 and 30 of US 11/145,459 are directed to a method and system for identifying related ions in a chromatography/mass spectrometry dataset comprising generating peak chromatograms from a dataset using peaks detected by detecting intensities of chromatograms, the input being a matrix with columns and rows corresponding to M/Z and time, correlating to form a correlation matrix, clustering the matrix, selecting a time period and producing a resultant spectrum.

While the instant claims do not require that the related ions come from a dataset generated from a chromatogram, US 2004/0096982 teaches that most mass spectrometers ionize molecules in a sample to be detected and that most spectrometers have the ability to fragment

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molecules. The detection of molecular fragments provides for information concerning the constitution of the molecule from which the fragments were derived. A separation procedure is often employed prior to injection of a sample into a mass spectrometer, to avoid complications associated with complex samples, such as proteins. Common procedures are those such as liquid chromatography, gas chromatography, and high performance liquid chromatography (paragraphs [0003 to 0004]).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used fragmentation via chromatography to include in the data set of the instant invention. One would have been motivated to do so because '982 states that this is often employed with mass spectroscopy to obtain better results of complex material, as stated above.

This is a provisional obviousness-type double patenting rejection.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

November 27, 2006

Lori A. Clow, Ph.D.

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Lori A. Clow
Patent Examiner
11/27/06